

FIG. 1

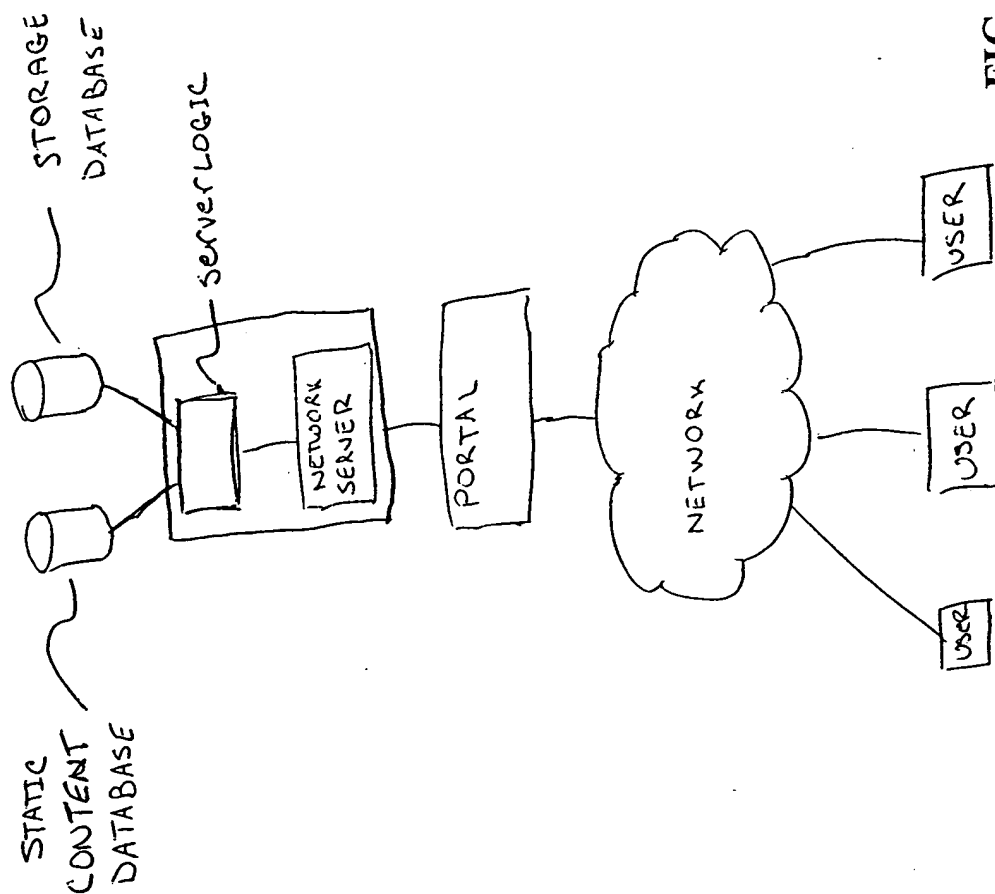


FIG. 2

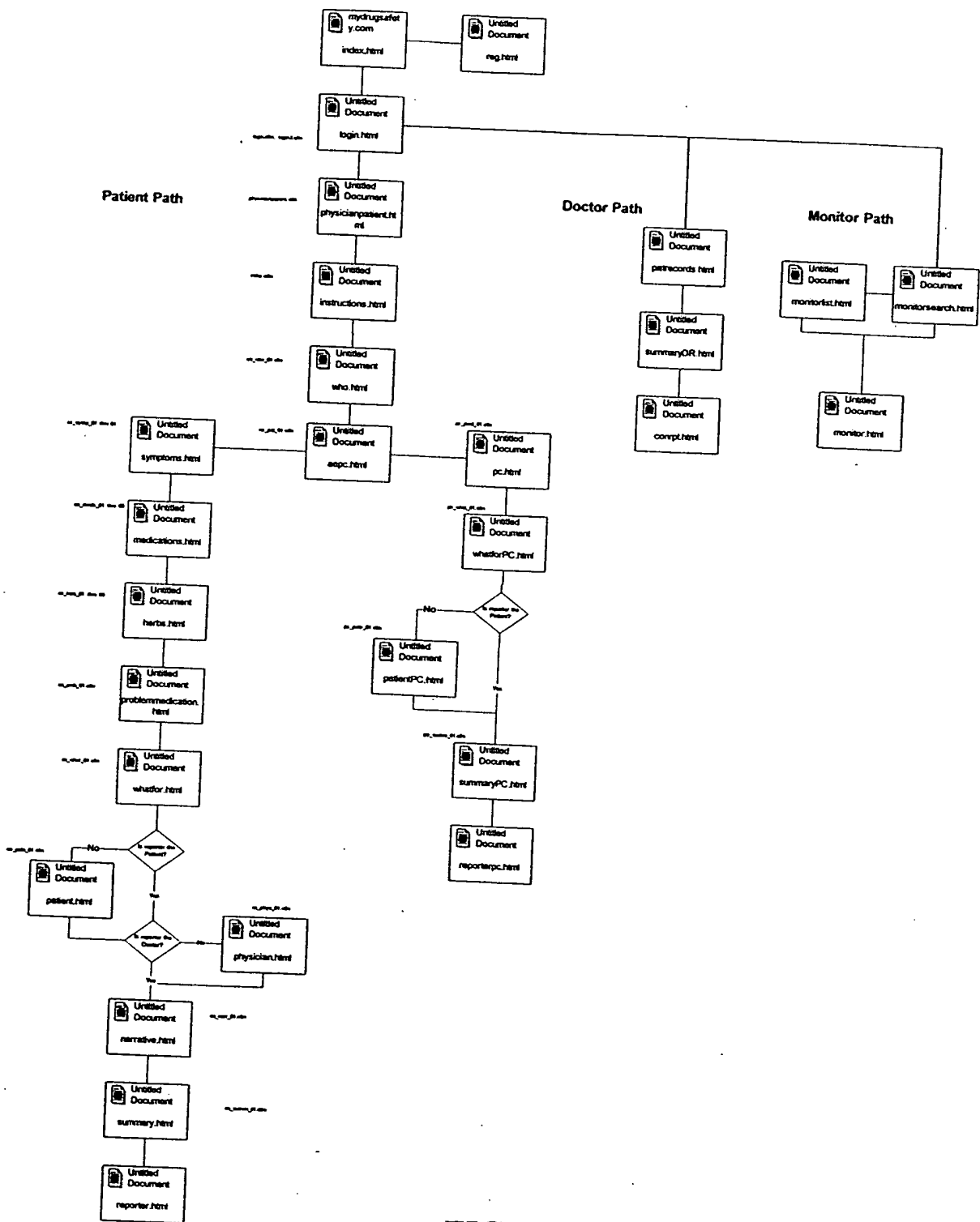


FIG. 3



Portal Pilot Workflow

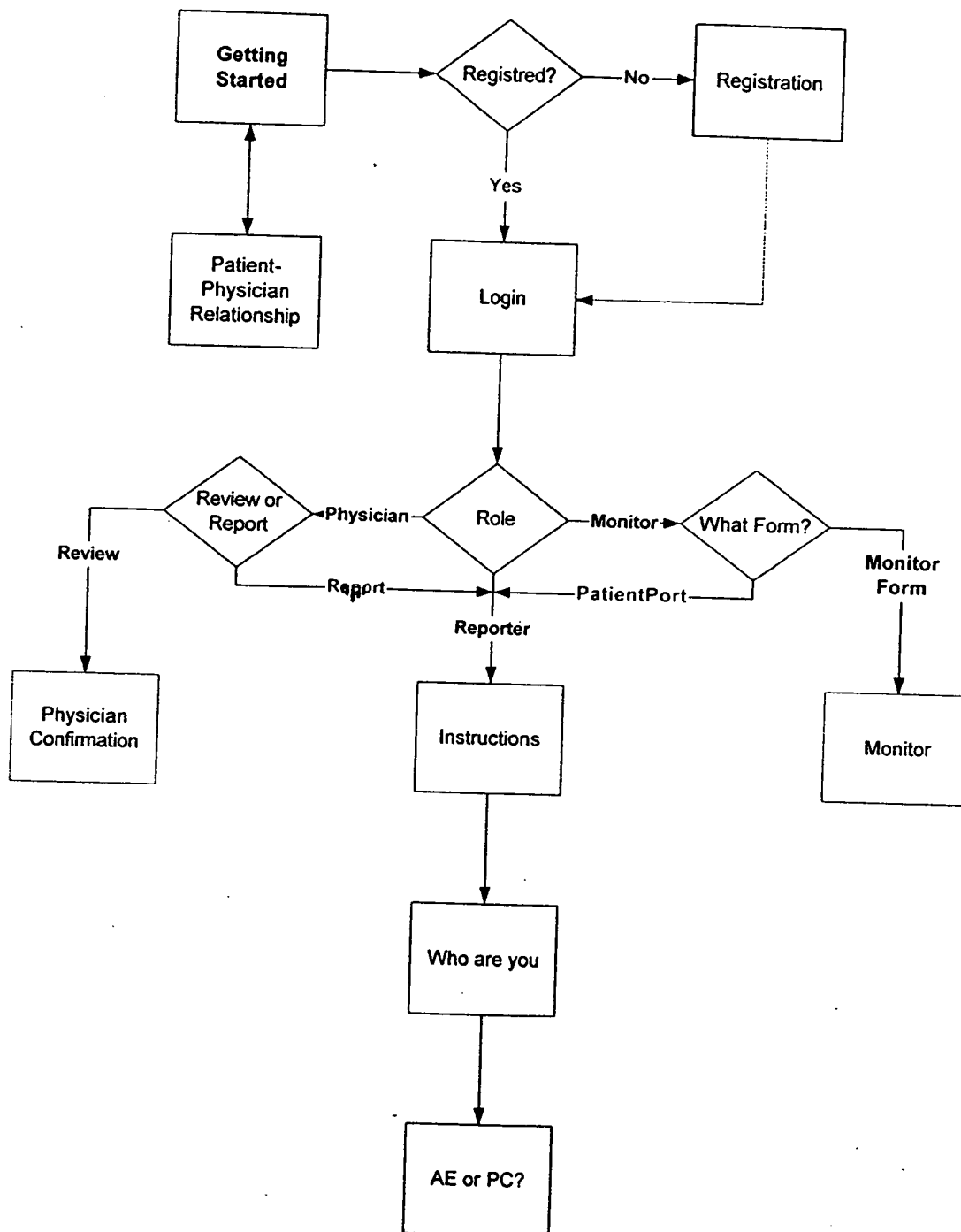


FIG. 3A



**AE or PC
Guided Reporting**

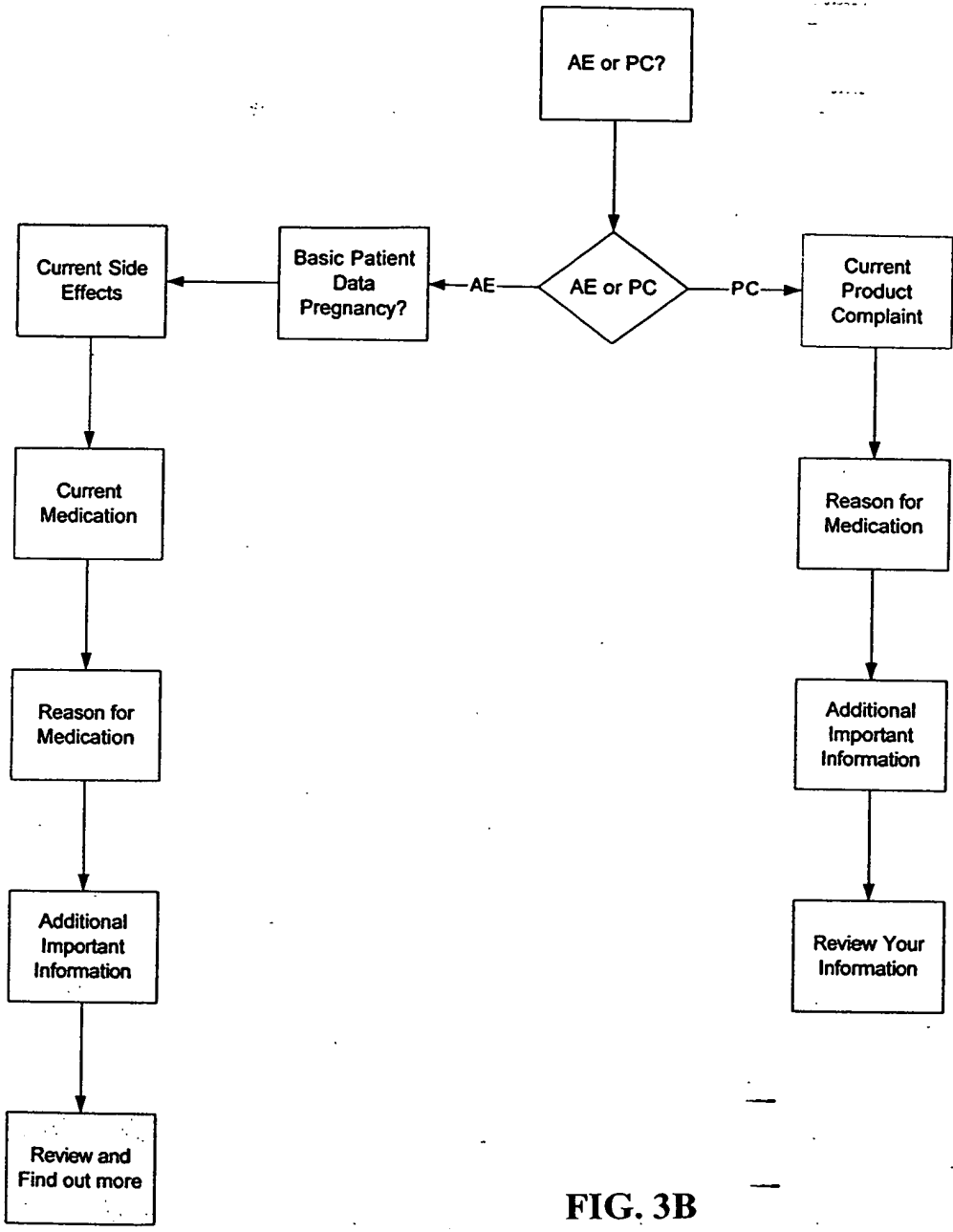


FIG. 3B

Physician Confirmation

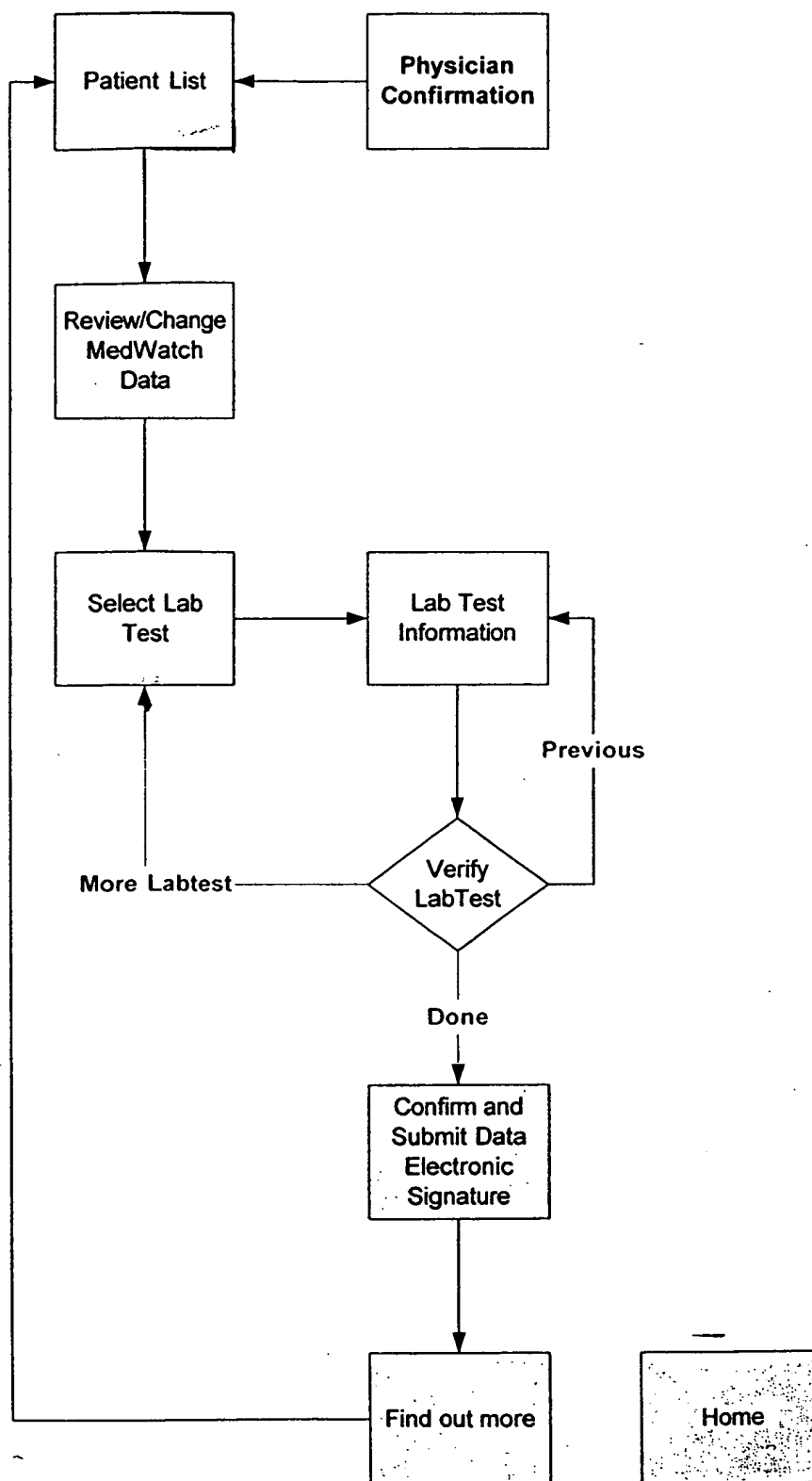


FIG. 3C



Monitor Form

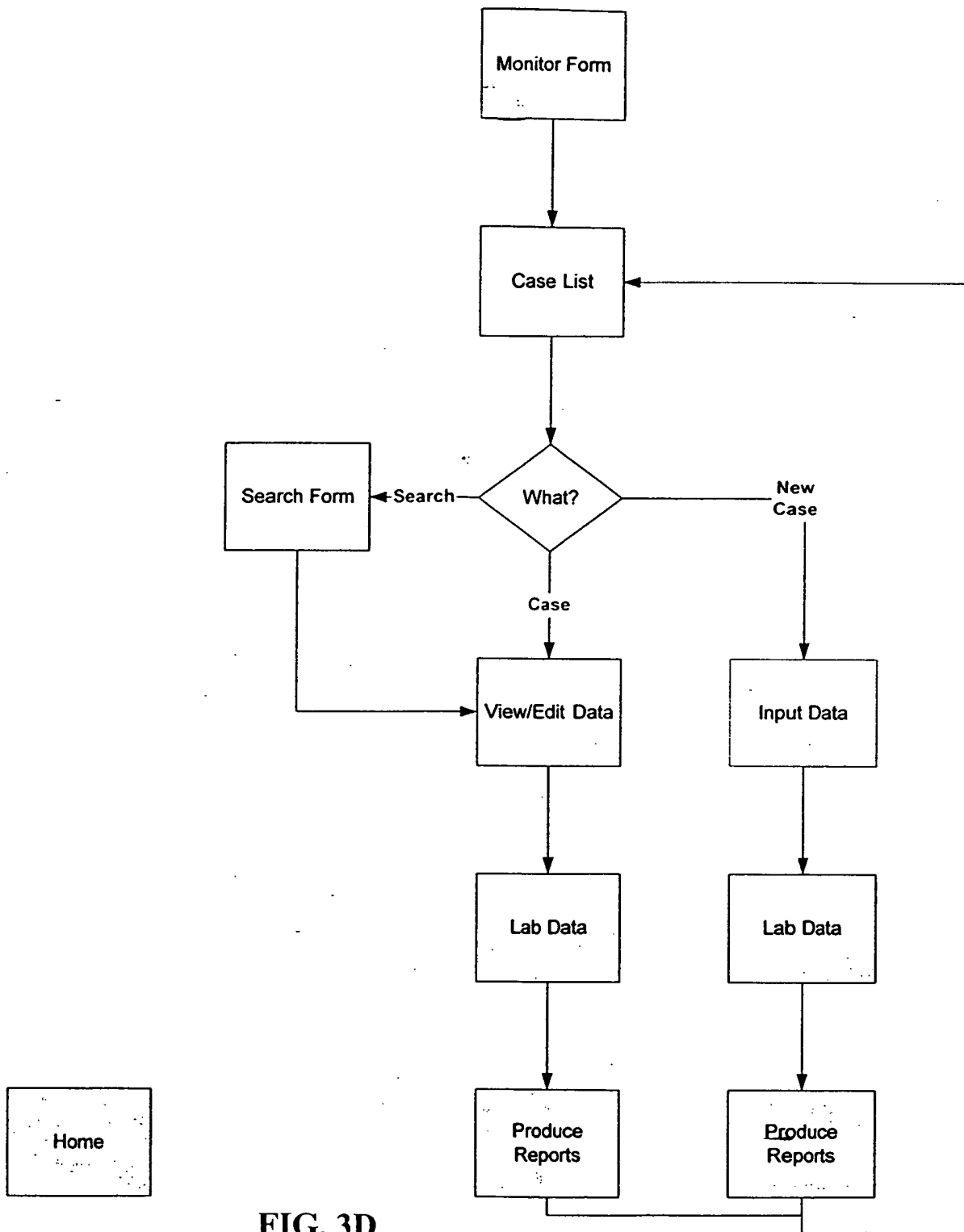


FIG. 3D



Current Side Effects

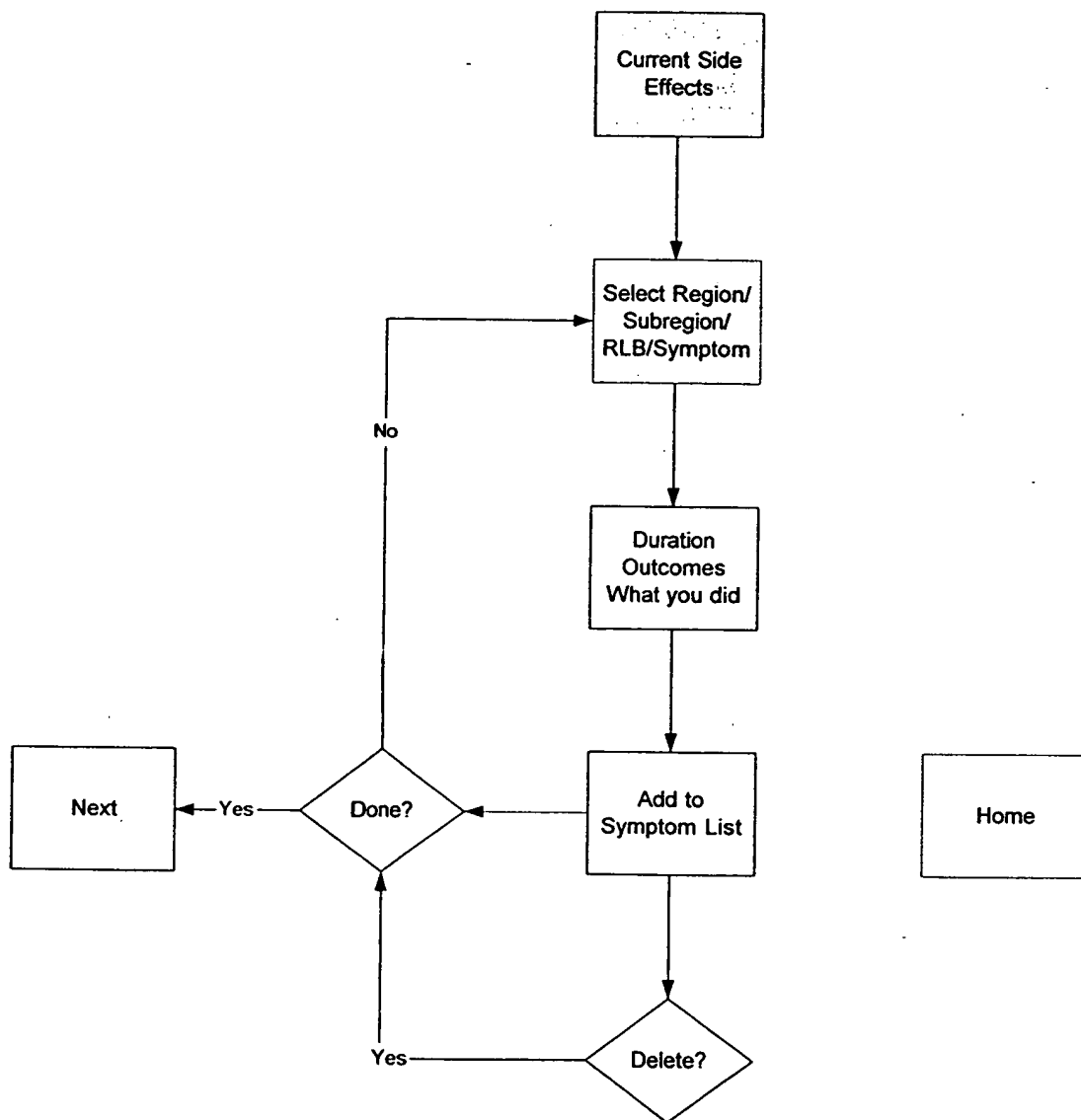


FIG. 3E



Current Medication

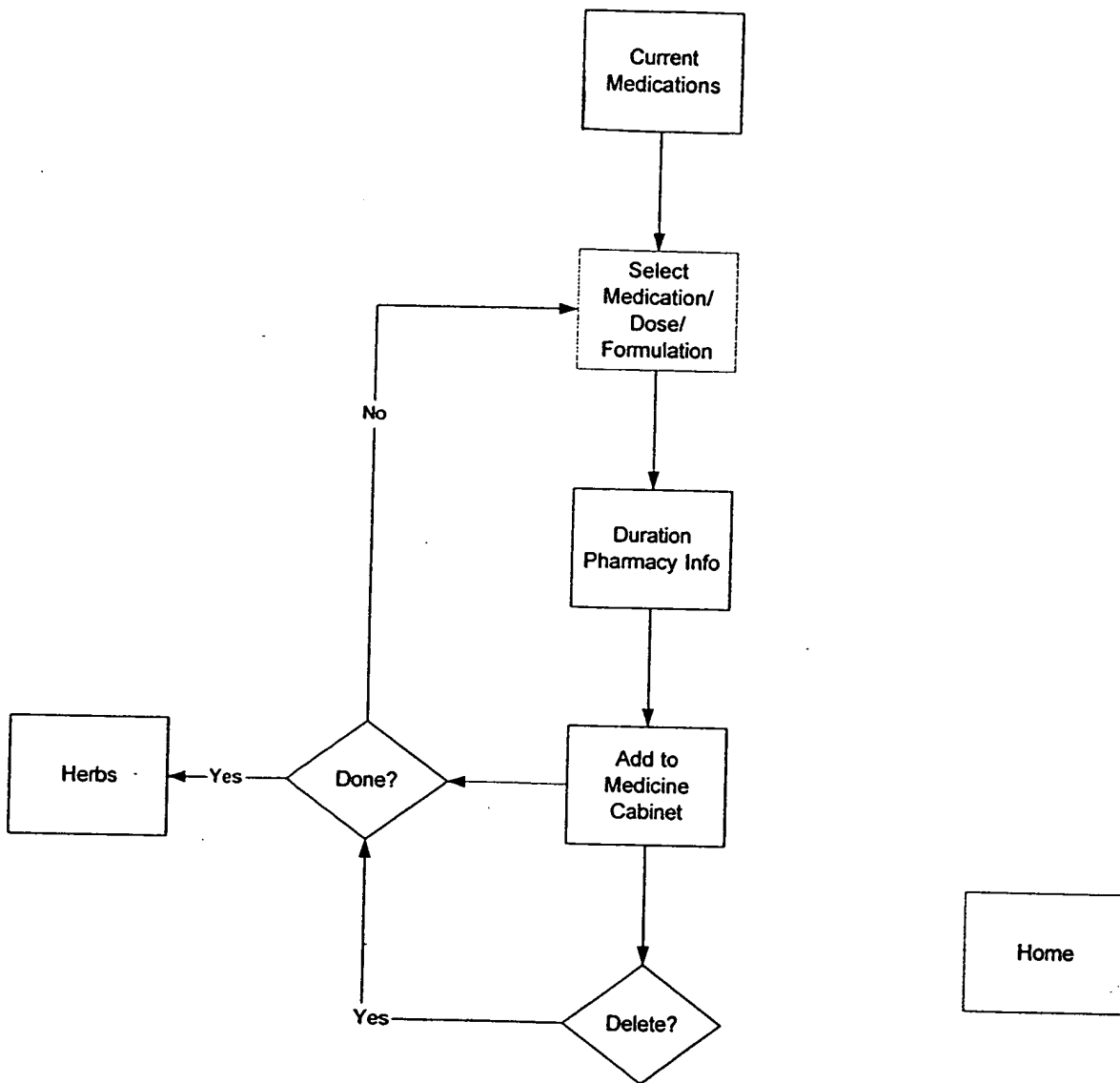


FIG. 3F



Herbs and Nutritional Supplements

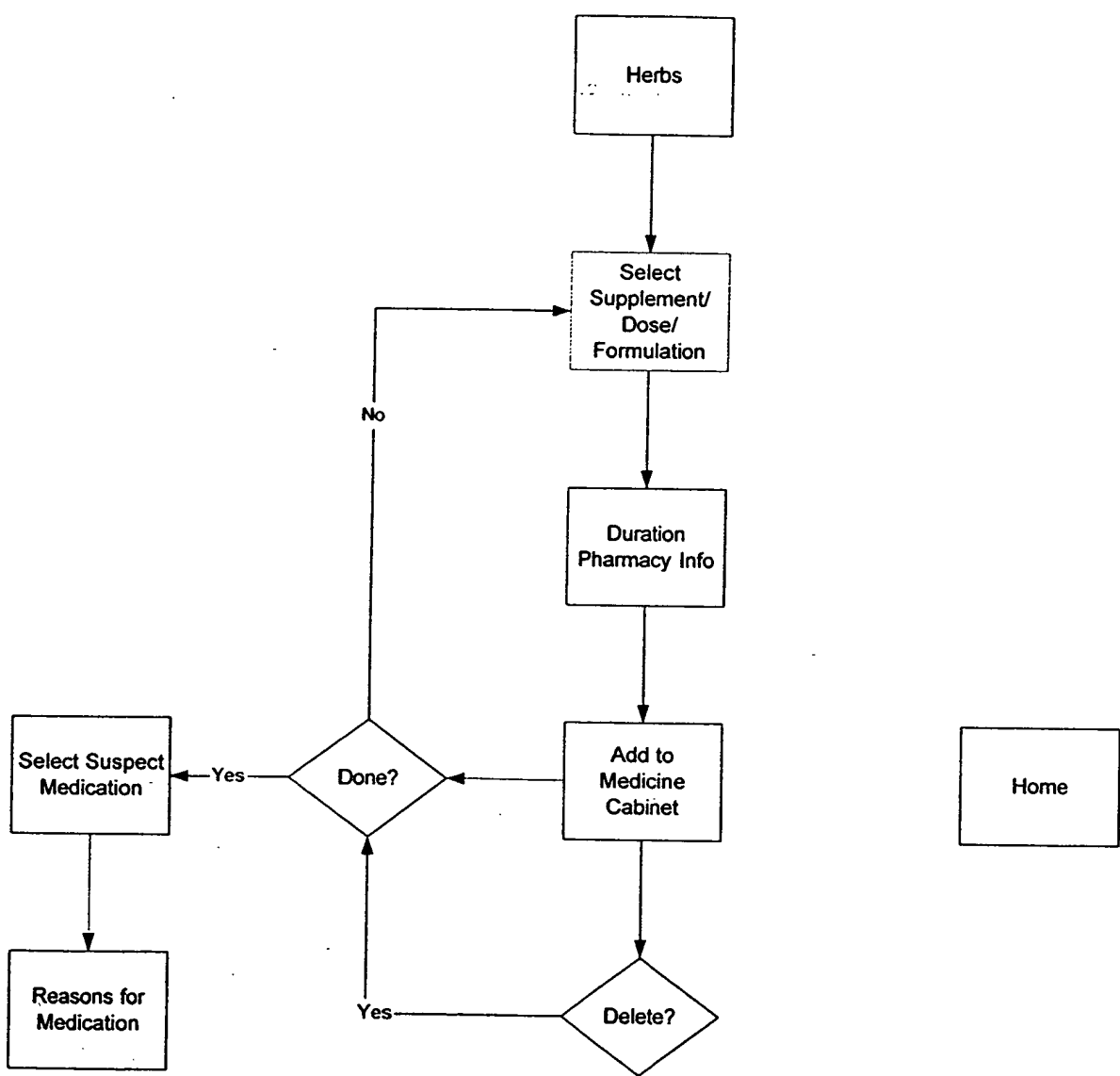


FIG. 3G



Reasons for Medication

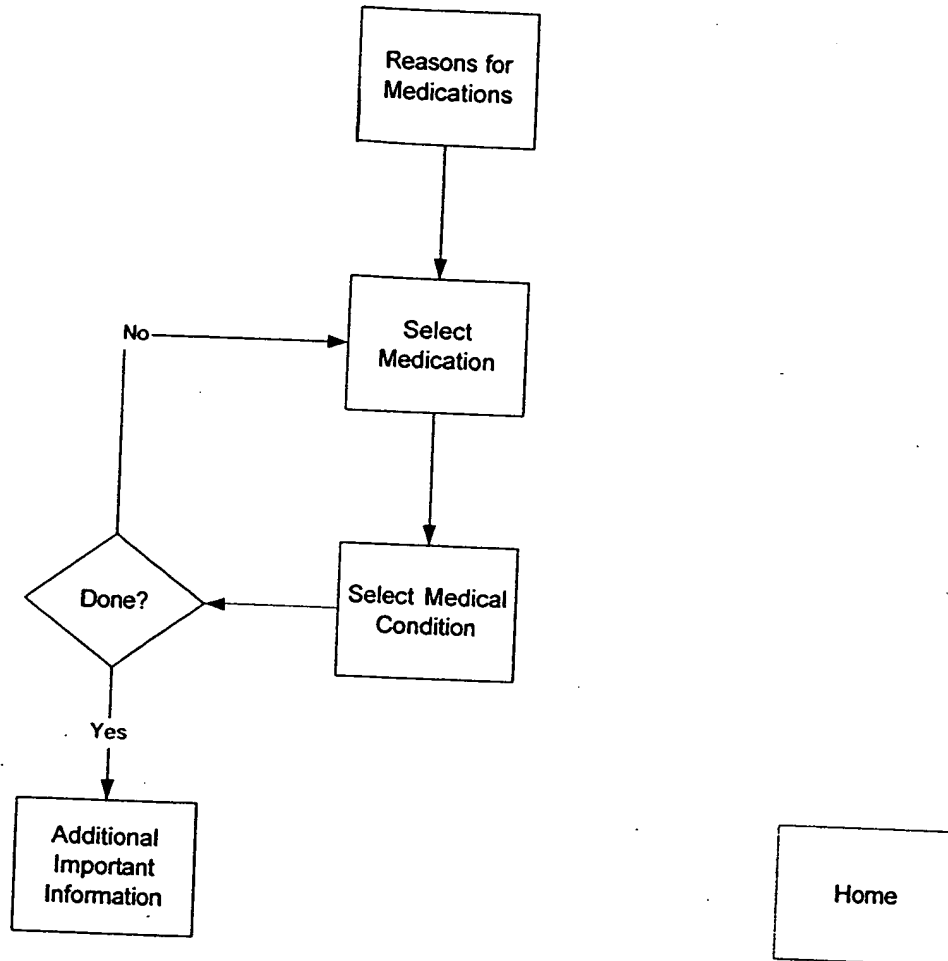


FIG. 3H



Additional Important Information

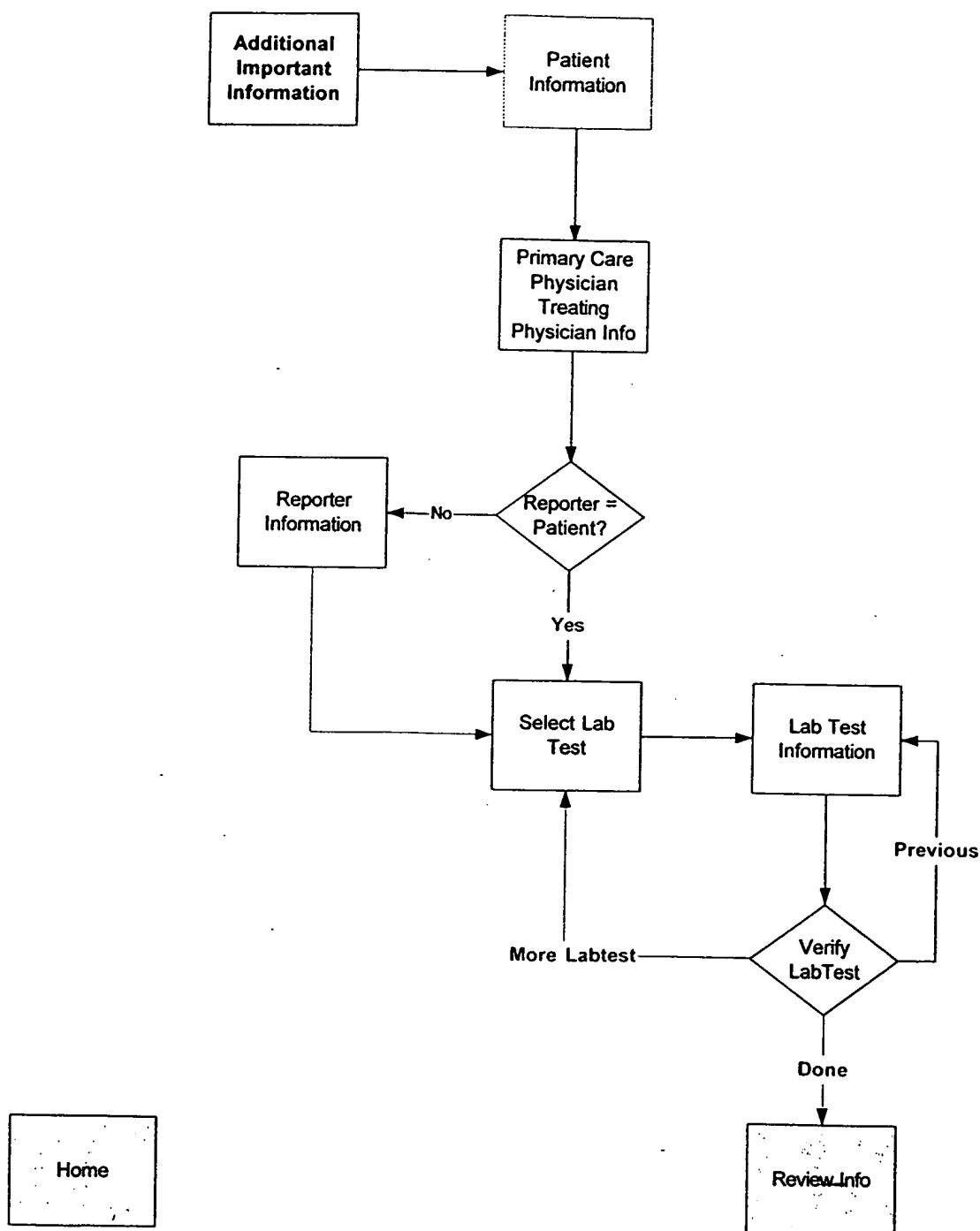


FIG. 3I



Review Information and Find out More

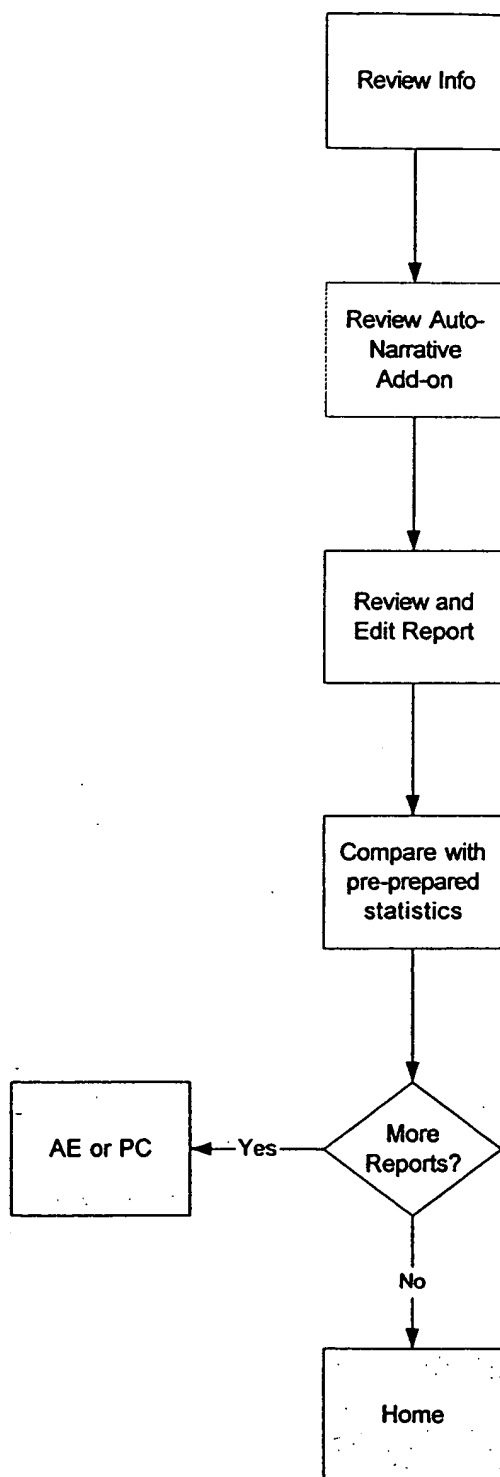


FIG. 3J

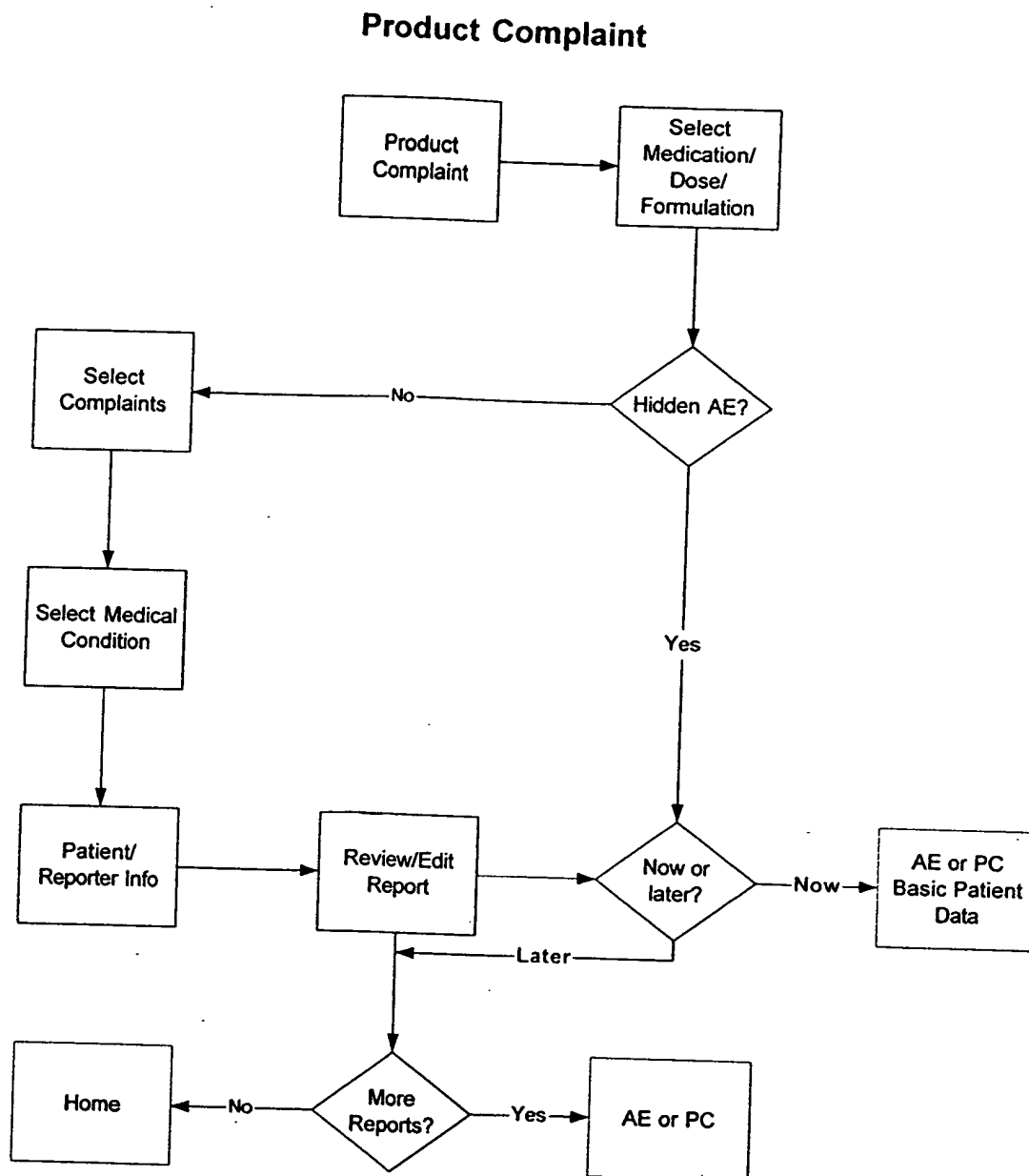


FIG. 3K



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Registration

Informed Consent

In order to complete the report, we may need to contact your physician. Your consent to contact your physician is called informed consent. Only your physician and you will see the information you provide us.

☐ **Accept**

(required to proceed)

This Web Portal is super-secure. To see your information, define a User-ID and password and log in. Forget your password? We can re-create it: 1) define a secret question (ex: What is my favorite football team) 2) define a secret answer (ex: the SF 49ers). Together these will identify you.

Getting Started

Login/Registration

Instructions

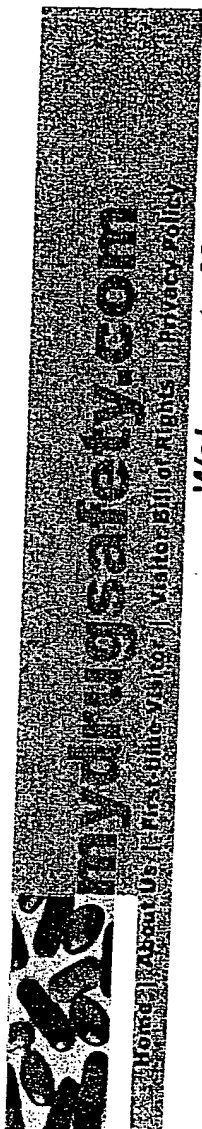
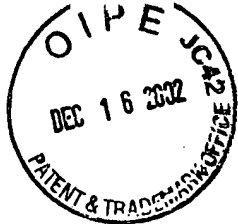
Who are you

Side Effects, and/or
Product Complaints

For this pilot, type the 8 digit registration code printed on your trial card.

First Name	<input type="text"/>
Last Name	<input type="text"/>
User ID	<input type="text"/>
Password	<input type="password"/>
Password again	<input type="password"/>
Secret Question	<input type="text"/>
Secret Answer	<input type="text"/>
Phone Number	<input type="text"/>
E-mail	<input type="text"/>

FIG. 4



Welcome to MyDrug Safety

Getting Started

First-time user? Go to our registration page.

You will need some information about your medication. As preparation, please get all your medication bottles, packets and containers.

Our reporting process contains 5 easy steps. At the end, you will receive a summary report for review.



The symbol provides online help. If you would like to read all the instructions for all the screens [click here to download](#).

UserID and Password ?

UserID

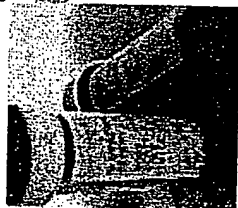
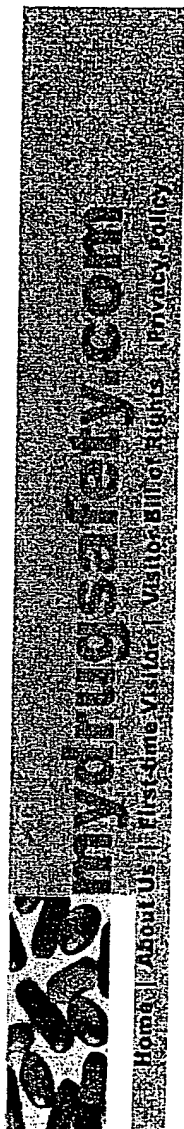
Password

Change your password?

New Password

Repeat Password

FIG. 5



Patient-Physician Relationship

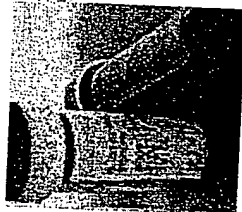
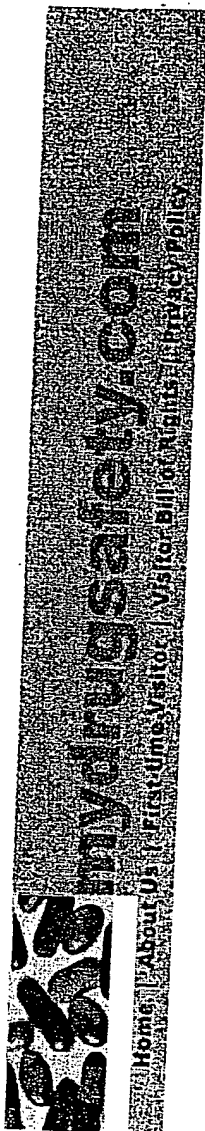
The Patient/Physician Relationship

To report your information properly, we have to have your physician confirm it. He will not only help you and us to make drugs safer, he can also help you with your side effect. Please provide us with your and your physician's information so that we can call or write back if we need more information. You can do this at any time by clicking on Registration or you will automatically be asked at the end of the process.

There appears to be an incomplete report in progress from the last time you were logged in. Do you want to recover it?



FIG. 6



Instructions

Easy steps to report a Side Effect or Adverse Event

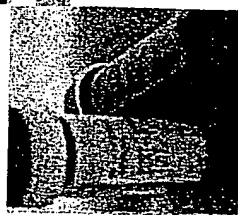
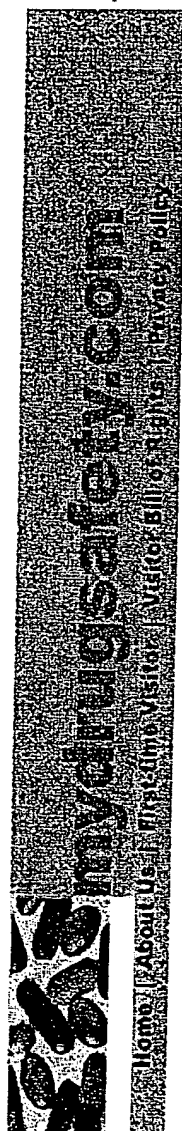
- STEP 1: Side effects or you are experiencing
- STEP 2: Medications you are taking
- STEP 3: Reasons for medication
- STEP 4: Additional Important Information
- STEP 5: Review your report and find out more

Easy steps to report a Product Complaint

- STEP 1: Product complaint
- STEP 2: Reason for medication
- STEP 3: Additional Important Information
- STEP 4: Review your report



FIG. 7



1 Getting Started
About MyDrugsSafety.com
Instructions
Who Are You?
Who Are You?
Side Effects and
Other Concerns

Who Are You?

2

Who Are You?

Family member/spouse

Patient

Patient Caretaker

Pharmaceutical Representative

Someone else? Who?

Treating physician
---Choose One---

Other Healthcare Professional
---Choose One---

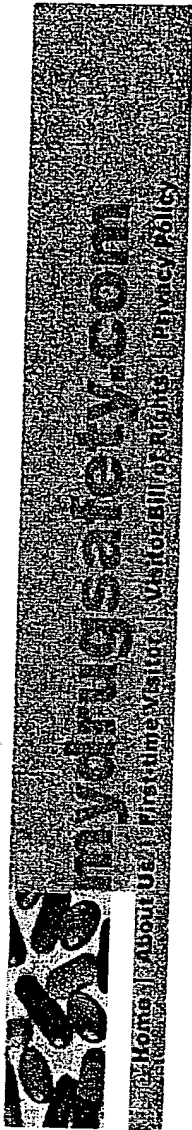
Previous Next

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Help

(helpscreens)

FIG. 8



Adverse Event or Product Complaint?

What Do You Want to Report?

☐ ADR ☐ PC

Adverse Reaction or a Side Effect you are having

Complaint about your medication



Family Members Data:

Date of Birth (mm-dd-yyyy)

or Age

Height feet inches
(ex: 5 feet 2 inches)

Weight lbs

☐ Male ☐ Female

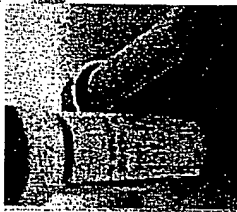
Pregnant ☒ YES



FIG. 9



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- 1 Getting started
- 2 Current Side Effects
 - What symptoms are you experiencing?
 - When did they start?
 - What results?
 - What you did?
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review info & Find Out More

Adverse Event Define a Symptom

Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

?

To delete a symptom from highlight it and press

Only when you have finished describing all your symptoms press

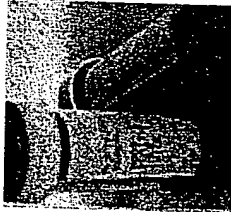
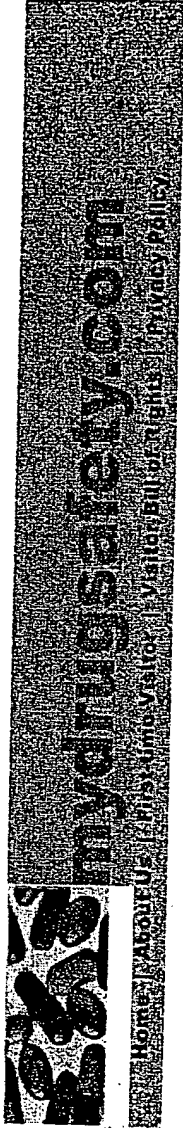
Click the region where the symptom occurs.:

or

REGION
Which area?:

Anus
Bladder
Buttocks
Cervix
Groin
Labia Minora/Majora
Ovaries
Rectum
Uterus
Vagina

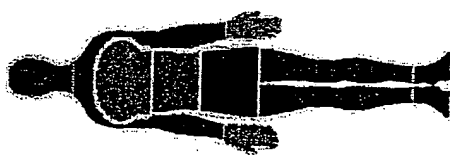
FIG. 10A



- 1 Getting Started
- 2 Current Side Effects
What symptoms
are you having?
Which body
parts are affected?
- 3 Current Medications
- 4 Reason for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

Adverse Event Define a Symptom

Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

Click the region where the symptom occurs.:	REGION Which area?:
	Right-Buttocks Left-Buttocks Both-Buttocks

or

?

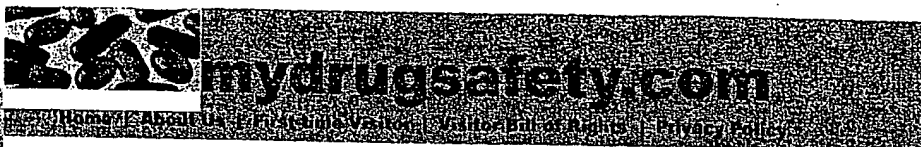
To delete a symptom from highlight it and press

Only when you have finished describing all your symptoms press

Delete

Delete

FIG. 10B



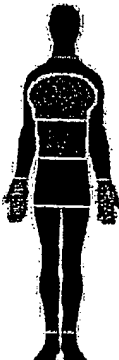
Adverse Event Define a Symptom

- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

To delete a symptom from highlight it and press

Only when you have finished describing all your symptoms press

Click the region where the symptom occurs:	REGION Which area?:	SYMPTOM What symptom?	DURATION	WHAT YOU DID ABOUT IT
 or General Body	Buttocks	Hip Pain	When did it start? (mm-dd-yyyy) When did it end? (mm-dd-yyyy) OR How Long did it last? Year Is it still there? <input type="checkbox"/> Yes RESULT What was the result of this event? <input type="checkbox"/> Hospitalized under 24 Hours <input type="checkbox"/> Hospitalized over 24 Hours <input type="checkbox"/> Disability <input type="checkbox"/> Congenital Anomaly <input type="checkbox"/> Intervention Needed <input type="checkbox"/> Life-Threatening <input type="checkbox"/> Died (mm-day-yyyy) Other <input type="checkbox"/>	<input type="checkbox"/> Did nothing <input type="checkbox"/> Consulted a Physician <input type="checkbox"/> Stopped Medication <input type="checkbox"/> Reduced dose to <input type="checkbox"/> Switched Medication to <input type="checkbox"/> Did it help? <input type="checkbox"/> Took Medication again and effect came back <input type="checkbox"/> Took something for it. What? Did it help? <input type="checkbox"/> YES Did something else

Help

(helpscreens)

FIG. 10C

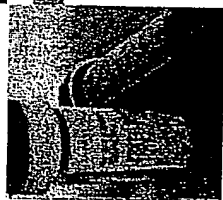


FIG. 11



What Medication Are You Taking? Suspect Medication

Please select the medication(s) that you think may have caused the event.		?
Your Current Medications Are <input checked="" type="checkbox"/> Lamisil		
<div>PREVIOUS</div> <div>NEXT</div>		



1. Current Medication

2. Current Side Effects

3. Current Medication
What to Do After
What to Do Before
What to Do After

4. Reason for Medication

5. Additional Important Information

6. Review and End of Survey

FIG. 12



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What Medication Are You Taking?

Herbs or Nutritional Supplements

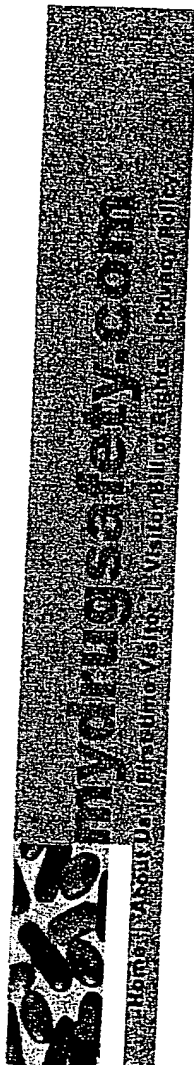
Herbs or Nutritional Supplements

<p>Tell us what herbs or other supplements you are taking.</p> <p>Click letter to choose from list.</p> <p>A B C D E F G H I J K L M N O P Q R S T U V W X Y Z</p>	<p>Pick one:</p> <p>_____ select a medication _____</p> <p>Not on the list? Enter below</p> <p>_____</p>	<p>Your Current Herbs</p> <p>_____ Your Current Medications _____</p> <p>& medicine & medicine </p>	<p>How long</p> <p>number of <input type="text"/> days</p> <p>Start <input type="text"/> mm-dd-yy</p> <p>End <input type="text"/> mm-dd-yy</p> <p><input type="checkbox"/> Still on it</p> <p>---optional info---</p> <p>Lot # of supplement? if present _____</p> <p>What Pharmacy did you purchase it at? _____</p> <p>name _____ zipcode _____</p>
<p>What Dose</p> <p>_____ select a dose _____</p> <p>Times a day <input type="text"/></p> <p>What Formulation?</p> <p>_____ what formulation _____</p>	<p>Add to Medicine Cabinet</p> <p>Delete</p> <p>Need To delete a medication from your current list? highlight it and press</p> <p>Done</p> <p>When your current medication list is complete press</p>	<p>?</p>	

- 1 Getting Started**
- 2 Current Side Effects**
- 3 Current Medications**
Medications
Herbs & Supplements
Problem Medication
- 4 Reasons for Medication**
- 5 Additional Important Information**
- 6 Review Info & Find Out More**

FIG. 13





Adverse Event What Are You Taking Your Medication For?

What condition are you taking your medication for? Click on your medication and a list of its associated condition/disease will appear. Select the appropriate one. Repeat for each medicine in the list.

Your Medication List			Medical Condition
Medication	Formulation	Dose Frequency (Times a Day)	
Lamisil	CREAM	1 % 4	-----select only one----- Not on the list?...Enter below
Previous Next			

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(helpscreens)

FIG. 14



- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
Patient Information
Physician Information
Lab Test Results
- 6 Review Info & Find Out More

Tell us what tests were done
Click letter to choose from list.

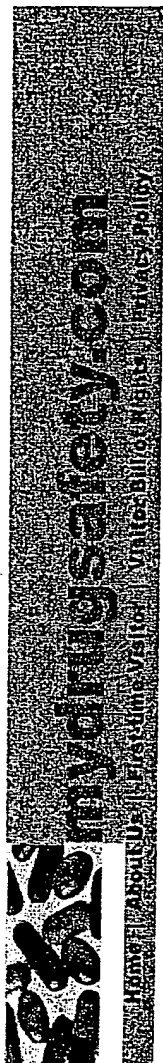
A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Then Select the appropriate test and method for the specimen, enter results. Standard Values for the test will be presented with an indicator for whether the patient values are within range or out of range.

Test	Specimen	Method	Min - Max	Test Value Measurement Time & Date	Status of Test
Albumin	Serum	Colimetry	3.5 - 5.0 g/dl	<input type="text"/> g/dl <input type="text"/> time <input type="text"/> <input type="text"/> dd <input type="text"/> mm <input type="text"/> year <input type="text"/>	<input type="text"/>
Aldolase				<input type="text"/> multiple test values at this date? <input type="text"/> g/dl <input type="text"/> time <input type="text"/> <input type="text"/> dd <input type="text"/> mm <input type="text"/> year <input type="text"/>	<input type="text"/>
Aldosterone				<input type="text"/> multiple test values at this date? <input type="text"/> g/dl <input type="text"/> time <input type="text"/> <input type="text"/> dd <input type="text"/> mm <input type="text"/> year <input type="text"/>	<input type="text"/>
Alkaline				<input type="text"/> multiple test values at this date? <input type="text"/> g/dl <input type="text"/> time <input type="text"/> <input type="text"/> dd <input type="text"/> mm <input type="text"/> year <input type="text"/>	<input type="text"/>
Phosphatase				<input type="text"/> multiple test values at this date? <input type="text"/> g/dl <input type="text"/> time <input type="text"/> <input type="text"/> dd <input type="text"/> mm <input type="text"/> year <input type="text"/>	<input type="text"/>

FIG. 14A





Adverse Event Product Complaint

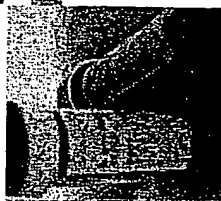
Check your record

This Report

<p>A -30Year old pregnant 1 patient, weighing 110 pounds, height 5 feet 6 inches, was taking Lamisil 1 & CREAM 4 Times a day since 07-01-2000, since [how long] [or continuing], for [indication/condition], reportedly experienced an event ['verbatim or reported' term/symptom (R/L/B)] on [date]. This report was received by [pharmaceutical company or GSS] on [date] from [reporter name].</p> <p>The patient was also taking [prescription medication, over-the-counter or nutraceutical products: concomitant drug 1 (dose, formulation, number of times/day, how long or continuing) for (indication/condition); concomitant drug 2 (dose, formulation, number of times/day, how long</p>

Anything to add?

Blabla

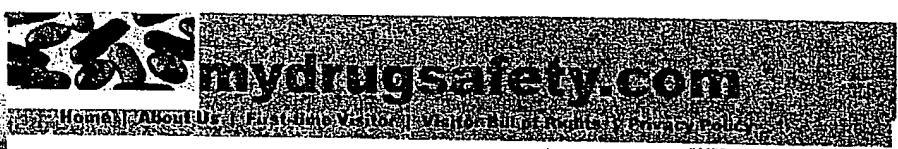


- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find our Mo's

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FIG. 15



Review Your & Who Record
Summary Report
pat1 patlast

Review and edit your report,



- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Edit or More

Type over text to edit and only when complete press **Update Report**

A. Patient Information

Patient Name pat1 patlast
Date of Birth 06-16-70
Age at Event -30
Gender ☐ Male ☐ Female
Pregnant? ☒ Yes ☐ No ☐ Unknown
Weight 110 Lbs
Height 5 feet 6 inches
(ex: 5 feet 2 inches)

B. Adverse Event

Results

☐ Died On (mm-day-yyyy)
☐ Hospitalized Less than 24 Hrs
☐ Hospitalized over 24 Hrs
☒ Disability
☐ Congenital Anomaly
☐ Intervention Needed
☐ Life Threatening
☐ Other

Date of Event (mm-dd-yyyy)

Date of Report 01-23-2001 (mm-dd-yyyy)

Description

Event Abated? ☐ Yes ☐ No ☐ Unknown
Event Reappeared? ☐ Yes ☐ No ☐ Unknown

C. Suspect Medications

Drug Name	Dose	Therapy Dates/Duration	Reason
Lamisil	1 %	From 07-01-2000 to 01-01-2001 Duration:1 Year	Disease 2

D. Concomitant Medication

Drug Name	Dose	Therapy Dates/Duration	Reason

Help

(helpscreens)

FIG. 16



PatientPortSM

Home | Wer wir sind | Erstmaliger Benutzer | Datenschutz | Logout

Arzneimittel-Nebenwirkungen Definieren Sie Das Symptom

1 Start
Login/Registrierung
Bedienungsanleitung
Wer sind Sie?
Arzneimittel-
Nebenwirkung oder
Beschwerde über das
Arzneimittel

2 Arzneimittel-Nebenwirkung
Ihre Symptome
Beginn und Ende
Direkte Auswirkungen
Gegenreaktionen

3 Ihre Medikamente
Medikamente
Andere Medikamente
Heilkräuter & Vitamine

4 Weshalb nehmen Sie?

5 Zusätzliche Informationen
Patienten-Report
Was Daten
...

6 Bestätigen Sie Ihre Daten
Ihr generierter Bericht
Alle Ihre Daten
Vergleich mit anderen
Berichten der FDA

Wir bitten Sie, im folgenden Ihre Arzneimittel-Nebenwirkungen zu beschreiben. Klicken Sie bitte eine Körperegion an und es wird eine Liste von Sub-Regionen erscheinen. Definieren Sie Ihr Symptom, indem Sie zuerst den genauen Ort bestimmen und dann ein Symptom aus der präsentierten Liste auswählen. Durch Anklicken der Figur können sie nachher weitere Regionen auswählen.

Ihre Symptome
Augen, verschwommene Sicht
Augen, verengte Pupillen

Um ein Symptom zu löschen, markieren Sie es bitte und drücken Sie **LÖSCHEN**
Erst wenn Sie alle Ihre Symptome abschliessend beschrieben haben, drücken Sie bitte **FERTIG**

Klicken Sie bitte die Region, in der Ihr Symptom sich äussert	KOPF Wählen Sie die Region?	SYMPTOM Ihr Symptom	DAUER	WAS UNTERNAHMEN SIE DAGEGEN?
	AUGEN	VERENGTE PUPILLEN	Beginn des Symptoms mm-dd-yy Ende des Symptoms mm-dd-yy Wie lange dauerte es? Tage <input checked="" type="checkbox"/> Besteht das Symptom immer noch? <input type="checkbox"/> JA	<input type="checkbox"/> Nichts <input type="checkbox"/> Konsultierte einen Arzt <input type="checkbox"/> Stoppte die Medikamenten-Einnahme Reduzierte die Medikamenten-Dosis auf <input type="text"/> <input type="checkbox"/> Wechselte das Medikament auf <input type="text"/>
			AUSWIRKUNG DES SYMPTOMS Hatte das Symptom direkte medizinische Auswirkungen, wie Hospitalisierung unter 24 Std <input checked="" type="checkbox"/>	Half es? <input type="checkbox"/> JA <input type="checkbox"/> Nahm das Medikament wieder und der Effekt erschien wieder <input type="checkbox"/> Nahm ein Gegenmittel. Was? <input type="text"/>
			SYMPTOM ZUR LISTE HINZUFÜGEN	

FIG. 16A

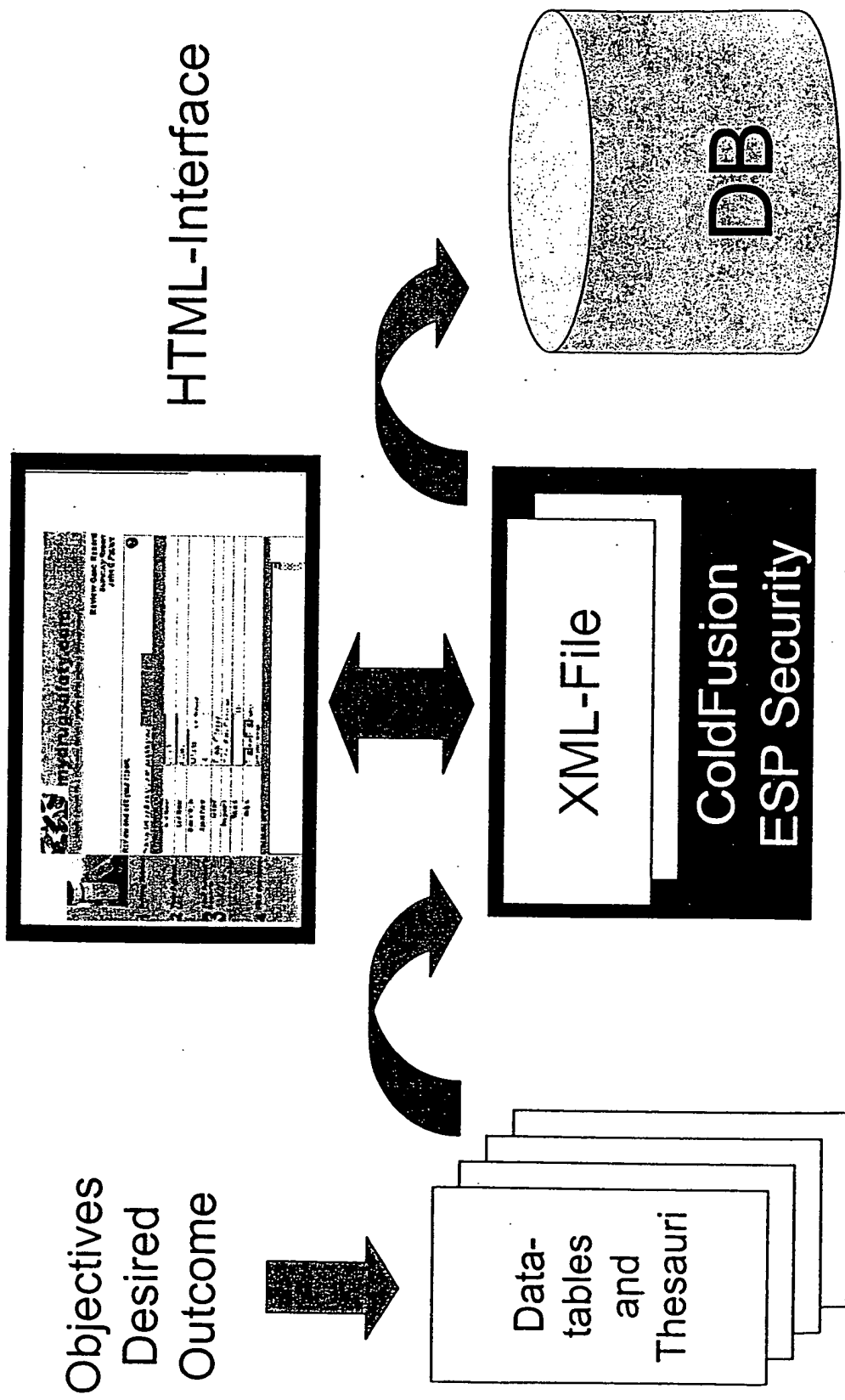


FIG. 17

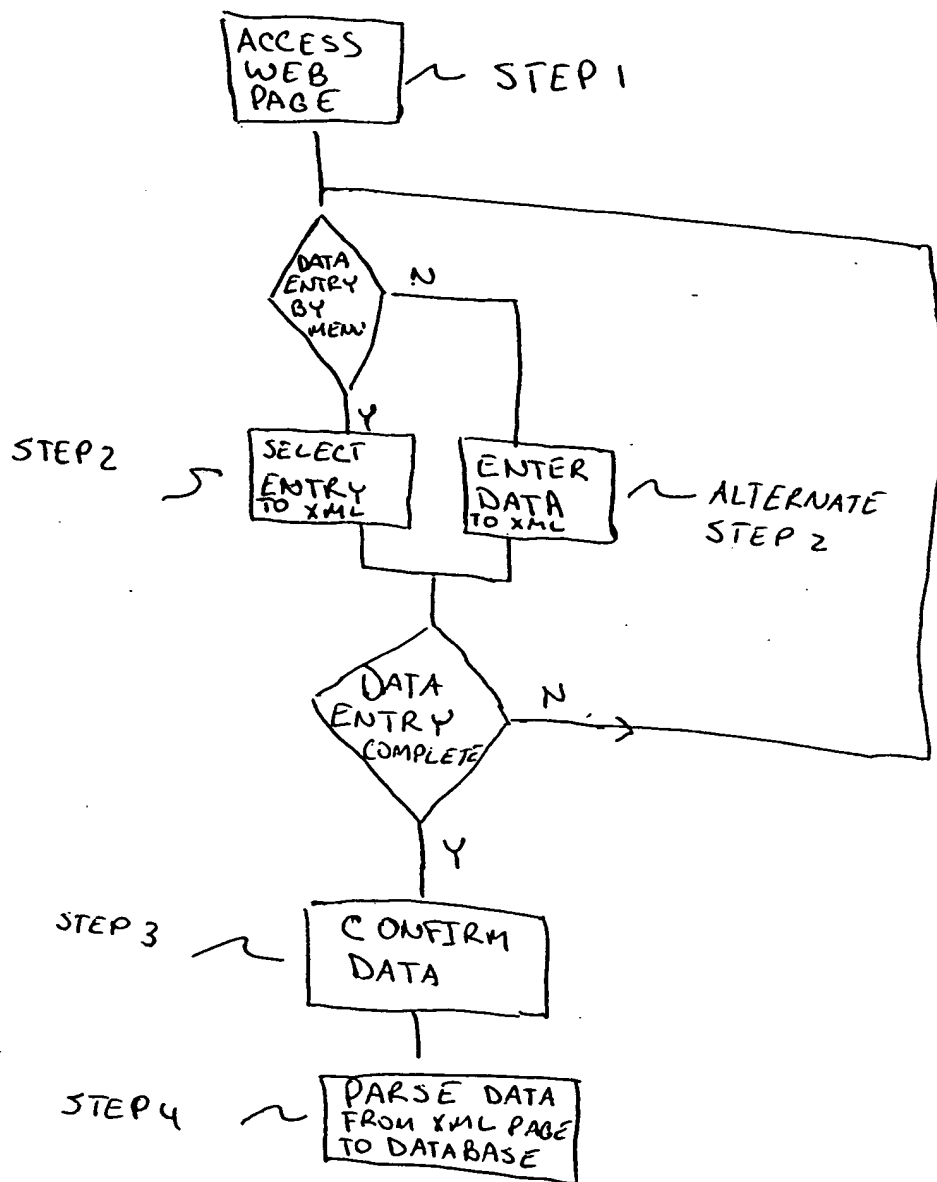


FIG. 18